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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,352	10/08/2003	Kyoji Ogoshi	3190-044	8311

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KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER

SIMS, JASON M

ART UNIT	PAPER NUMBER
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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/681,352	Applicant(s) OGOSHI, KYOJI	
	Examiner Jason M. Sims	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of group I, claims 25-26 in the reply filed on 3/12/2007 is acknowledged. The traversal is on the ground(s) that the scope of the claims of group II fall within the scope of the claims of group I. This is not found persuasive because the two inventive groups involve determining what amino acids are encoded at a unique group of positions and then correlating those amino acids with a cancer treatment, which the determined encoded amino acids at the two unique groups of positions requires unique method steps of correlating those unique groups of amino acids with a cancer treatment. The related inventions are distinct because they have a materially different design, mode of operation, function, or effect.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 27-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/12/2007.

Claims 25-26 are the current claims hereby under examination.

Priority

The instant application is a continuation of PCT/JP02/02894 filed on March 26, 2002. The benefit of priority is not granted for the two foreign applications filed in Japan as requested in the declaration because the instant application does not comply with the rules set out in 35 U.S.C. § 119 (a)-(d): namely, a certified copy of the original foreign application has not been filed with the Office. Applicants are requested to comply with

these rules, if possible, or withdraw claims to priority benefits. Therefore, this Office action considers prior art before the earliest effective filing date of March 26, 2002.

Claim Objections

Claim 25 is objected to because of the following informalities: Claim 25 contains several acronyms, each of which should be appropriately identified with their full names. For example, claim 25 contains the acronym HLA DQB1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 line 1, recites "a method for determining treatments for a cancer patient" in the preamble while the method steps, lines 2-12 are directed to method steps, which result in correlating encoded amino acid positions with a cancer treatment, which causes claim 25 to be vague and indefinite. The metes and bounds of claim 25 is not clear because it is not clear whether the preamble reciting "a method for determining treatments for a cancer patient", or the method steps control the metes and bounds of said claim 25.

Claim 25 contains the word “correlating,” which has been deemed as vague and indefinite. It is unclear as to what exactly the word “correlating” refers. It is unclear as to what is involved or how the method step of “correlating” encoded amino acids at particular positions with a cancer treatment is performed. Clearer claim wording is required.

Claim 25 contains the wording “the positions,” at line 10, which has been deemed as vague and indefinite. It is unclear as to which positions of which gene are being referred as antecedent basis has been established with reference to three different groups of “positions” on three different genes. It appears that “the positions” may reference all positions on any of the three genes referenced. Clearer claim wording is required.

Claim 25 contains the wording “statically significant probability,” which has been deemed vague and indefinite. It is unclear as to what exactly the word “statically” refers. Clearer claim wording is required.

Claim 25 contains the wording “the greatest statically significant probability” in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 contains the wording “the cancer patient comprises stomach cancer,” which is deemed as vague and indefinite. It appears that the claim is citing wherein the cancer of the patient comprises stomach cancer. However, it is unclear as to what exactly the wording “the cancer patient comprises stomach cancer” refers. Clearer claim wording is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (J. Clinical Oncology, vol. 19, pp. 1279-1287, 2001) in view of Lee et al. (Gastroenterology, vol. 111, pp. 426-432, 1996) and further in view of Santamaria et al. (US P/N 5,972,604).

The claims are directed to a method for determining treatments for a cancer patient comprising of determining what amino acids are encoded by one or more of a number of positions of the HLA DQB1 *gene, determining what amino acids are encoded by one or more of a number of positions of the DRB1 *gene, determining what amino acids are encoded by one or more of a number of positions of the DPBI *gene, and correlating the amino acids encoded at the positions with a cancer treatment having the greatest statistically significant probability of prolonging the cancer patient's survival,

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wherein the cancer treatment comprises immunotherapy, chemotherapy, resection, or a combination thereof.

Davies et al. teach a method for evaluating cancer treatments based on genotyping polymorphic genes of patients receiving cancer therapy and correlating the survival results of patients containing a specific polymorphic gene with appropriate cancer treatment regimens (see abstract, p. 1279). The reference teaches that the polypeptide encoded by polymorphic genes of Glutathione S-transferase, i.e., namely theta (GSTT1) and mu (GSTM1), affect the cytotoxicity of chemotherapeutic drugs. Experimental DNA typing data of Glutathione S-transferase polymorphic genes were obtained from a patient population of children with acute myeloid leukemia or AML (see Table 1 and GST Genotyping, p. 1280) receiving chemotherapy (see Chemotherapy Treatment Regimen). GSTT1 and GSTM1 genotype outcome differences in overall survival, disease-free survival and relapse-free survival were statistically analyzed (see Statistical Analysis, p 1280, Figures 1-5, pp.1281-1282, and Tables 2-3, pp. 1282-1283) and further lead to the conclusion that children lacking GSTT1 had greater toxicity and reduced survival rate after chemotherapy for AML compared with children with at least one GSTT1 allele, wherein the genotype might be of useful in selecting appropriate chemotherapy regimens for children with AML (see last paragraph of p. 1284).

Davies et al. does not teach any association of HLA class II genes with any cancer. However, the references of Lee et al. (see line 1-2, col. 1, p. 426) and Santamaria et al. (col. 3, lines 1-67, col. 4, lines 1-7, col. 9, lines 60-68, and col. 10, lines 1-16) teach HLA Class II genes are associated with several cancers, including the

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DRB1, DQB1, and the DPB1 genes. Namely, "HLA-DQB1*0310 is more common in Caucasian patients with gastric adenocarcinoma than noncancer controls" (Lee et al. see conclusions, p. 426).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to use the genotyping methods of Davies et al. or Lee et al. or Santamaria et al. along with the statistical methods of Davies et al. to identify HLA Class II polymorphic genes of patients receiving cancer therapy and correlating the survival results of HLA Class II genotype with appropriate cancer treatment regimens. Because of the extensive cancer polymorphic genotyping of Lee et al. and Santamaria et al. and the productive results of cancer polymorphic genotyping of Davies et al., one would have been motivated by Davies et al. who states that "This study shows that pharmacogenetic factors can influence the outcome of therapy, and particularly dose-intensive therapy" to combine the references.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla can be reached via telephone (571)-272-0735.

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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

Lori A. Claus
Primary Patent Examiner
5/29/07